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1651

PATENT  
2059-0103P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Harold G. BROWN et al. Conf.: 1812  
Appl. No.: 09/890,425 Group: 1651  
Filed: February 19, 2002 Examiner: Prats  
FOR: A PHARMACEUTICAL COMPOSITION OF COMPLEX  
CARBOHYDRATES AND ESSENTIAL OILS AND METHODS  
OF USING THE SAME

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

January 30, 2004

Sir:

The following information is being provided consistent with Applicants' duty of disclosure. This information was brought to the attention of the undersigned as a result of Interrogatories in another application. The Interrogatories discuss products that are alleged to be material to the other application. These products are ARTHRICARE and FLEXALL.

**ARTHRICARE**

Neither the inventors nor the undersigned had any information with respect to the ingredients of ARTHRICARE at the time the application was filed. Applicants do not concede that ARTHRICARE is material to the prosecution of the present application since Applicants do not know if this product(s) was on the market prior to filing of the present application. Applicants do not know the composition of ARTHRICARE that may have existed prior to the time of filing the present application.

The undersigned recently conducted a quick on-line search for the product ARTHRICARE and ordered this product on-line. The undersigned visited at least five local stores and was unable to purchase the product directly. The following information concerning ARTHRICARE is not prior art since the products were purchased in November of 2003, which is almost four years after the International filing date of the present application and almost five years after the first filed provisional application. The following information is taken from the box for the product(s) and/or is printed on the tube containing the product.

A first product is "ARTHRICARE For Women" "Multi-Action". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%), menthol USP 1.25% and methyl nicotinate 0.25%. The inactive ingredients are listed as follows: aloe vera gel, carbomer, cetearyl alcohol (and) cetearyl glucoside, decyl glucoside, methylparaben, propylene glycol, propylparaben and titanium dioxide. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is a cream and is said to be greaseless. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2001."

A second product is "ARTHRICARE For Women," "Ultra Strength". The active ingredients are capsicum oleoresin

(containing capsaicin 0.075%) and menthol 2%. The inactive ingredients are listed as follows: butylene glycol, carbomer, cetearyl alcohol (and) sodium cetearyl sulfate, cetyl alcohol, diazolidinyl urea, dimethicone, disodium EDTA, di-alpha tocopheryl acetate, glycerin, octyldodecanol, PEG-8 beeswax, phenoxyethanol (and) methylparaben (and) ethylparaben (and) butylparaben (and) propylparaben (and) isobutylparaben, purified water and triethanolamine. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is a cream. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A third product is "ARTHRICARE For Women," "Silky Dry". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%). The inactive ingredients are listed as follows: colloidal silicone dioxide, fragrance, isopropyl myristate (and) isopropyl palmitate (and) isopropyl stearate, methylparaben, mineral oil, polyethylene, propylparaben, retinyl palmitate with cholecalciferol and dl-alpha tocopheryl acetate. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is said to go on dry. The box has the following

information on it: "© Del Pharmaceuticals, Inc. 2001."

A fourth product is "ARTHRICARE For Women," "Nighttime". The active ingredients are methyl salicylate 30%, menthol USP 1.25% and methyl nicotinate 0.25%. The inactive ingredients are listed as follows: carbomer 940, dioctyl sodium sulfosuccinate, FD&C Blue #1, glycerin, isopropyl alcohol, polysorbate 60, propylene glycol and purified water. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and sprains. The product is said to be greaseless. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A fifth product is "ARTHRICARE For Women," "Extra Moisturizing". The active ingredients are capsicum oleoresin (containing capsaicin 0.025%). The inactive ingredients are listed as follows: allantoin, aloe vera gel, caprylic/capric triglyceride, carbomer, cetyl alcohol, dimethicone, fragrance, methylparaben, mixed fruit complex (citric acid, green tea extract, lactic acid, malic acid), PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, propylparaben, purified water, quaternium-15, sodium citrate, stearyl alcohol and titanium dioxide. No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor aches and pains of muscles and joints due to simple backache, arthritis and strains and

sprains. The box has the following information on it: "© Del Pharmaceuticals, Inc. 2000."

A copy of the front and back of each of the five products are attached hereto.

FLEXALL

FLEXALL is referenced in the application as filed. More specifically, FLEXALL 454 is discussed on page 6 of the application in the "Background and field of the Invention" as follows:

Essential oils are natural components of plants and animals that are extracted by various methods known to the art. They are generally very complex, containing numerous compounds (see Perfumer and Flavorist, 17, Nov/Dec 1992). More recently, some of the essential oils have been chemically synthesized. Most uses of these oils are as flavorings for foods and candies and as bath, cosmetic and perfume ingredients to provide pleasant aromas. Several of the essential oils (i.e. Menthol, Eucalyptus Oil, Camphor, Peppermint Oil and Wintergreen Oil) are currently used in over-the-counter topical preparations such as BenGay, Mineral Ice, Flexall 454, etc. at concentrations as high as 50%. These topical medications claim pain relief but, according to FDA, act to relieve pain by producing a counterirritation, not by penetrating the skin and acting systemically to reduce inflammation and swelling which are the causes of pain.

The undersigned did not conduct an on-line search for this product since the relevant information known to Applicant at the time of filing the application was disclosed in the specification. The inventors have no further information concerning this product.

The undersigned purchased "FLEXALL Plus" at a local store in November 2003. The active ingredients are camphor 3.1%, menthol 16% and methyl salicylate 10%. The inactive ingredients are

listed as follows: allantoin, aloe barbadensis leaf juice, carbomer, diisopropyl adipate, eucalyptus globules leaf oil, glycerin, mentha piperita (peppermint) oil, SD alcohol 40 (15% w/w), steareth-2, steareth-21, thymus vulgaris (thyme) oil, tocopheryl acetate, triethanolamine and water (234-97). No amounts are listed for the inactive ingredients. The disclosed uses are for temporary relief of minor pain associated with arthritis, simple backache, muscle strains, muscle sprains, bruises and cramps. The product is said to be greaseless. The box has the following information on it: "Dist. By Chattem, Inc.... ©2002."

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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Falls Church, VA 22040-0747  
(703) 205-8000

MSW/sh  
2059-0103P



EXTRA MOISTURIZING  
ARTHRITIS PAIN RELIEF  
FORMULATED FOR WOMEN

# ArthriCare

FOR WOMEN

## EXTRA MOISTURIZING

ARTHRITIS PAIN RELIEVING CREAM

- EXTRA MOISTURIZING FORMULA
- FAST-ACTING/  
LONG-LASTING RELIEF
- ALPHA HYDROXY  
AND ALOE TO SOFTEN  
AND MOISTURIZE SKIN
- PLEASANT FRAGRANCE

Women's  
Arthritis  
Pain Relief

NET WT 4 fl oz (118ml)

Also try other  
ArthriCare®  
Arthritis Pain  
Relieving Products:

- ArthriCare® for Women Quick-Drying Formula: Arthritis pain relief in a patented, quick-drying formula.
- ArthriCare® for Women Multi-Action Formula: Triple-action arthritis pain relief plus soothing aloe.
- ArthriCare® for Women Nighttime Formula: 3 pain relievers for warming, fast-acting pain relief to help you sleep.

LOT 251 EXP 06



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7529

# ArthriCare®

## FOR WOMEN

EXTRA MOISTURIZING

ARTHRITIS PAIN RELIEVING CREAM

### Drug Facts

Active ingredient	Purpose
Capsicum oleoresin (containing capsaicin 0.025%)	Topical analgesic

**Uses** temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains and sprains

### Warnings

For external use only

**Do not use**

- with a heating pad
- immediately before or after taking a shower or bath

**When using this product**

- do not get into eyes
- do not bandage tightly
- temporary redness may occur
- avoid contact with mucous membranes, broken or irritated skin

**Stop use and ask a doctor if**

- symptoms last for more than 7 days
- symptoms clear up and occur again within a few days
- condition gets worse

**Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

- adults and children 2 years and older: apply to affected areas not more than 3 to 4 times daily
- children under 2 years: ask a doctor

### Other information

- store at room temperature 15° - 30° C (59° - 86° F)

**Inactive ingredients** allantoin, aloe vera gel, caprylic/capric triglyceride, carbomer, cetyl alcohol, dimethicone, fragrance, methylparaben, mixed fruit acid complex (citric acid, green tea extract, lactic acid, malic acid), PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, propylparaben, purified water, quaternium-15, sodium citrate, stearyl alcohol, titanium dioxide

**Questions or comments?** Call us at 1-800-952-5080

DEL PHARMACEUTICALS, INC.  
a subsidiary of Del Laboratories, Inc., Farmingdale, NY 11735  
© Del Pharmaceuticals, Inc., 2000

Made in U.S.A.

ArthriCare® has a powerful arthritis pain relief cream with extra moisturizers to meet the needs of women with arthritis and dry skin. ArthriCare for Women Extra-Moisturizing Formula is an advanced 2-in-1 formula that combines a powerful doctor-recommended pain blocker with extra moisturizers, Alpha Hydroxy and Aloe for soft, smooth skin.

347529000

NIGHTTIME ARTHRITIS PAIN RELIEF  
FORMULATED FOR WOMEN

# ArthriCare<sup>®</sup> FOR WOMEN

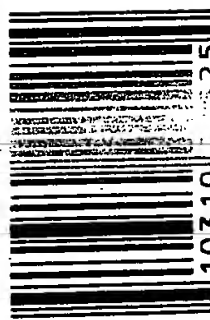
ARTHRITIS PAIN RELIEVING CREAM

- NIGHTTIME FORMULA RELIEVES PAIN  
TO HELP YOU SLEEP
- TRIPLE-MEDICATED FOR WARMING,  
FAST-ACTING RELIEF
- GREASELESS, ABSORBS EASILY

Women's  
Arthritis  
Pain Relief

NET WT 1.1 oz (31g)

LOT C8253



347525000

ArthriCare<sup>®</sup>  
FOR WOMEN

ARTHRITIS PAIN RELIEVING CREAM

9  
9/00  
P61704

## Drug Facts

### Active Ingredients

Methyl salicylate 30% ..... Topical analgesic  
Menthyl USP 1.25% ..... Topical analgesic  
Menthyl nicotinate 0.25% ..... Topical analgesic

### Purpose

..... Topical analgesic  
..... Topical analgesic  
..... Topical analgesic

### Uses

temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache ■ arthritis ■ strains and sprains

### Warnings

For external use only

Do not use ■ on wounds or damaged skin ■ with a heating pad, or immediately before or after taking a shower or bath

### When using this product

- do not get into eyes ■ avoid contact with mucous membranes, broken or irritated skin

■ do not bandage tightly ■ temporary redness may occur

### Stop use and ask a doctor if

- condition gets worse ■ symptoms last for more than 7 days or clear up and occur again within a few days

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### Drug Facts (continued)

### Directions

- read package insert before using
- adults and children 2 years and older: apply to affected areas not more than 3 to 4 times daily
- children under 2 years: ask a doctor

### Other information

- store at room temperature 15° - 30° C (59° - 86° F)

### Inactive ingredients

carbomer 940, dioctyl sodium sullosuccinate, FD&C Blue #1, glycerin, isopropyl alcohol, polysorbate 60, propylene glycol, purified water

ArthriCare® has a specially formulated powerful arthritis pain relief cream to meet the needs of women who experience arthritis pain and are looking for effective nighttime relief. ArthriCare for Women Nighttime Formula is a greaseless, triple-medicated formula that absorbs easily, combining 3 pain relievers for warming, fast-acting pain relief to help you sleep.

**ArthriCare®**  
FOR WOMEN

ARTHRITIS PAIN RELIEVING CREAM

### DEL PHARMACEUTICALS, INC.,

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ULTRA STRENGTH ARTHRITIS PAIN RELIEF  
FORMULATED FOR WOMEN

# ArthriCare<sup>®</sup> FOR WOMEN

ULTRA STRENGTH

ARTHRITIS PAIN RELIEVING CREAM

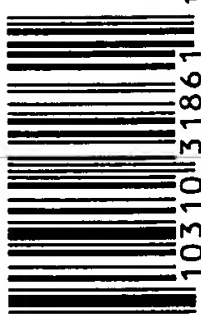
Women's  
Arthritis  
Pain Relief

- HIGH POTENCY FORMULA
- TRIPLE-STRENGTH
- ARTHRITIS PAIN RELIEF

NET WT 1.5 oz (42.5g)

LOT90451  
EXP10/04

347561002



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ArthriCare<sup>®</sup>  
FOR WOMEN

ULTRA STRENGTH  
ARTHRITIS PAIN RELIEVING CREAM

## Drug Facts

<b>Active Ingredients</b>		<b>Purpose</b>
Capsicum oleoresin (containing capsaicin 0.075%)		Topical analgesic
Menthol 2%		Topical analgesic
<b>Uses</b> temporarily relieves minor aches and pains of muscles and joints due to:		
■ simple backache ■ arthritis ■ strains and sprains		
<b>Warnings</b>		
For external use only		
Do not use ■ with a heating pad, or immediately before or after taking a shower or bath		
When using this product		
■ do not get into eyes ■ do not apply to wounds or damaged skin ■ do not bandage tightly		
Stop use and ask a doctor if ■ condition gets worse ■ symptoms last for more than 7 days		
■ symptoms clear up and occur again within a few days		
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		
<b>Directions</b> read package insert before using		
Adults and children 2 years and older		apply to affected areas not more than 3 to 4 times daily
Children under 2 years		consult a doctor

## Drug Facts (continued)

<b>Other Information</b> ■ as part of the warming action, temporary redness may occur	
■ store at room temperature 15° - 30° C (59° - 86° F)	
<b>Inactive Ingredients</b> butylene glycol, carbomer, cetearyl alcohol (and) sodium cetearyl sulfate, cetyl alcohol, diazolidinyl urea, dimethicone, disodium EDTA, dl-alpha tocopheryl acetate, glycerin, octyldodecanol, PEG-8 beeswax, phenoxyethanol (and) methylparaben (and) ethylparaben (and) butylparaben (and) propylparaben (and) isobutylparaben, purified water, triethanolamine	

ArthriCare® has a powerful, high potency arthritis pain relief cream to meet the needs of women who experience arthritis pain and want a higher potency pain reliever. ArthriCare for Women Ultra Strength Formula is a triple strength, creamy formula combining a powerful doctor-recommended pain blocker plus a second pain reliever for fast-acting, long-lasting and deep penetrating pain relief.

**ArthriCare®**  
FOR WOMEN

ULTRA STRENGTH  
ARTHRITIS PAIN RELIEVING CREAM

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INSTANT DRYING ARTHRITIS PAIN RELIEF  
UNIQUELY FORMULATED FOR WOMEN

# ArthriCare<sup>®</sup> FOR WOMEN

SILKY DRY

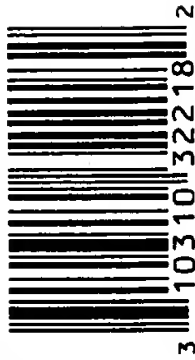
ARTHRITIS PAIN RELIEVING CREAM

*Women's  
Arthritis  
Pain Relief*

NET WT. 1.5 OZ (42.5g)

LOTAD364 EXP10/04

- PATENTED FORMULA GOES ON DRY
- FAST-ABSORBING, FAST-RELIEF
- VITAMINS E AND A TO NOURISH  
AND MOISTURIZE SKIN
- PLEASANT POWDER - FRESH SCENT



347372001

**ArthriCare<sup>®</sup>**  
**FOR WOMEN**

SILKY DRY  
ARTHRITIS PAIN RELIEVING CREAM

## Drug Facts

<b>Active Ingredient</b> Capsicum oleoresin (containing capsaicin 0.025%)		<b>Purpose</b> Topical analgesic
<b>Uses</b> temporarily relieves minor aches and pains of muscles and joints due to: ■ arthritis ■ simple backache ■ strains and sprains		
<b>Warnings</b> For external use only		
<b>Do not use</b> ■ with a heating pad, or immediately before or after taking a shower or bath		
<b>When using this product</b> ■ do not get into eyes ■ do not bandage tightly ■ do not apply to wounds or damaged skin		
<b>Stop use and ask a doctor if</b> ■ condition gets worse ■ symptoms last for more than 7 days ■ symptoms clear up and occur again within a few days		
<b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		
<b>Directions</b> read package insert before using		
Adults and children 2 years and older	Apply to affected areas not more than 3 to 4 times daily	
Children under 2 years	Ask a doctor	

## Drug Facts (continued)

<b>Other information</b> ■ as part of its warming action, temporary redness may occur ■ store at room temperature 15°-30°C (59°-86°F)	
<b>Inactive Ingredients</b> colloidal silicone dioxide, fragrance, isopropyl myristate (and) isopropyl palmitate (and) isopropyl stearate, methylparaben, mineral oil, polyethylene, propylparaben, retinyl palmitate with cholecalciferol, di-alpha tocopheryl acetate.	

ArthriCare® has a revolutionary, powerful arthritis pain relief cream uniquely formulated to meet the needs of women with arthritis. ArthriCare for Women Silky Dry Formula is a patented formula that goes on dry, combining a powerful doctor-recommended pain blocker with a powder-fresh fragrance and Vitamins E and A to nourish and moisturize the skin.

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U.S. Patent Number 5,178,881

For more information call 1-800-952-5080 or visit [www.arthricare.com](http://www.arthricare.com)

**ArthriCare®**  
**FOR WOMEN**

**SILKY DRY**  
**ARTHRITIS PAIN RELIEVING CREAM**

TH FORMULA

5/02  
P151110

**33%  
MORE  
FREE**

THAN 1.5 oz SIZE

MULTI-ACTION ARTHRITIS PAIN RELIEF  
FORMULATED FOR WOMEN

**ArthriCare®  
FOR WOMEN**

**MULTI-ACTION**

ARTHRITIS PAIN RELIEVING CREAM

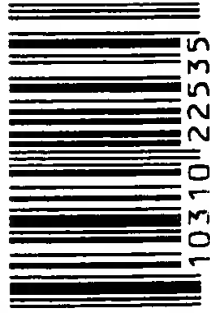
Women's  
Arthritis  
Pain Relief

NET WT 2.0 oz (56.7g)

LOTAC371  
EXP11/04

- MULTI-ACTION PAIN RELIEF FORMULA
- FAST-ACTING, LONG-LASTING  
DEEP PENETRATING
- WITH SOOTHING ALOE

347535800



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**ArthriCare®  
FOR WOMEN**

**MULTI-ACTION**  
ARTHRITIS PAIN RELIEVING CREAM



## Drug Facts

<b>Active Ingredients</b>		<b>Purpose</b>
Capsicum oleoresin (containing capsaicin 0.025%)	.....	Topical analgesic
Menthol USP 1.25%	.....	Topical analgesic
Methyl nicotinate 0.25%	.....	Topical analgesic
<b>Uses</b> temporarily relieves minor aches and pains of muscles and joints due to:		
■ simple backache ■ arthritis ■ strains and sprains		
<b>Warning</b>		
For external use only		
Do not use ■ with a heating pad, or immediately before or after taking a shower or bath		
When using this product ■ do not apply to wounds or damaged skin ■ do not get into eyes ■ do not bandage tightly		
Stop use and ask a doctor if		
■ condition gets worse ■ symptoms last for more than 7 days ■ symptoms clear up and occur again within a few days		
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		

## Drug Facts (continued)

<b>Directions</b> read package insert before using	
adults and children 2 years and older	apply to affected areas not more than 3 to 4 times daily
children under 2 years	ask a doctor
<b>Other Information</b> ■ as part of its warming action, temporary redness may occur	
■ store at room temperature 15° - 30° C (59° - 86° F)	
<b>Inactive Ingredients</b> aloe vera gel, carbomer, cetearyl alcohol (and) cetearyl glucoside, decyl glucoside, methylparaben, propylene glycol, propylparaben, titanium dioxide	

ArthriCare® has a powerful pain relief cream in a multi-action formula to meet the unique needs of women who experience arthritis pain. ArthriCare for Women Multi-Action Formula is a triple action, greaseless formula, combining a powerful doctor-recommended pain blocker plus two added pain relievers for fast-acting, long-lasting and deep penetrating pain relief, plus Aloe to soothe a woman's sensitive skin.

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For more information call 1-800-952-5080 or visit [www.arthricare.com](http://www.arthricare.com)

**ArthriCare®**  
**FOR WOMEN**

**MULTI-ACTION**  
ARTHRITIS PAIN RELIEVING CREAM

10/01  
P120624

**Triple Action**  
**Powerful Full Speed Pain Relief**  
**With 3 Proven Pain Relievers**

**PENETRATING RELIEF FROM PAINFUL  
MUSCLES AND JOINTS DUE TO:**

Arthritis Backache Muscle Strains and Sprains  
**GREASELESS STAINLESS EASY TO APPLY**

0044527-01

**Maximum Strength**  
**FLEXALL<sup>®</sup>**  
**Plus**

**Maximum Strength**  
**Flexall<sup>®</sup>**  
**Plus**

Pain Relieving Gel

Net Wt 2 OZ (56.69g)



004452701



004452701

**Maximum Strength**  
**Flexall<sup>®</sup>**  
**Plus**

Pain Relieving Gel

**Maximum Strength**  
**Flexall<sup>®</sup>**  
**Plus**

Maximum Strength Flexall<sup>®</sup> Plus has a Triple Action formula with the maximum level of a pain reliever, the most of any pain rub, plus two additional pain relievers for Triple Action relief that penetrates deep, heats fast and relieves quickly.

#### Drug Facts

##### Active ingredients

Camphor 3.1%

Menthol 16%

Methyl salicylate 10%

##### Purpose

Topical analgesic

Topical analgesic

Topical analgesic

Uses temporarily relieves minor pain associated with:

■ muscle sprains ■ bruises ■ cramps

■ arthritis ■ simple backache ■ muscle strains

##### Warnings

For external use only

Allergy alert: Do not use if you are allergic to salicylates (including aspirin) unless directed by a doctor.

When using this product ■ use only as directed ■ do not bandage tightly or use a heating pad ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin

Stop use and ask a doctor if ■ condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ irritation develops

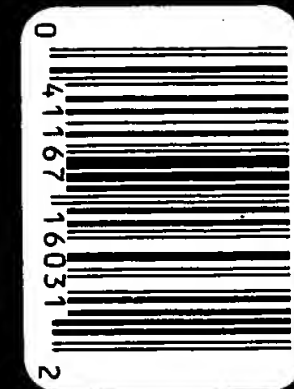
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

##### Directions

adults and children over 12 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily children 12 years or younger: ask a doctor

**Inactive ingredients** allantoin, aloe barbadensis leaf juice, carbomer, diisopropyl adipate, eucalyptus globulus leaf oil, glycerin, mentha piperita (peppermint) oil, SD alcohol 40 (15% w/w), steareth-2, steareth-21, thymus vulgaris (thyme) oil, tocopheryl acetate, triethanolamine, water (234-97)



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**Maximum Strength**  
**Flexall<sup>®</sup>**  
**Plus**